Instructions for use
Boule Con

Revision history

Latest revision: October 2023. Previous revision: June 2022

Changes: Added Swiss authorized representative. Document updated for IVDR and for clarity and conformity, all information either added or updated.

Intended purpose and user requirements

- Boule Con-Diff is intended for monitoring the performance of white blood cells (WBC); the absolute number and percentage for granulocytes (GRA), lymphocytes (LYM), mid-sized white cells (MID); red blood cells (RBC); hemoglobin (HGB); mean cell volume of red cells (MCV); hematocrit (HCT); mean cell hemoglobin (MCH); mean cell hemoglobin concentration (MCHC); red cell distribution relative width (RDW%); platelets (PLT); mean platelet volume (MPV). of on Medonic M-series and Swelab Alfa hematology analyzer.
- The controls are intended for professional use. Operator must have basic laboratory skills, be aware of good laboratory practice, and read the user manual before use.

Summary and principles

Boule Con Hematology Control is prepared from stabilized human blood so that repeated measurements can be made daily to monitor the performance of hematology analyzer systems. ASSIGNED VALUES and EXPECTED RANGES are determined on systems using specific Boule reagents. ASSIGNED VALUES are confirmed by multiple analysis of the control product and should be considered a **suggested average** until you establish your own running mean.

Reagents

Boule Con contains treated, stabilized human erythrocytes and a stabilized platelet-sized component in an isotonic, bacteriostatic medium. Fixed erythrocytes are added to simulate leukocytes.

Storage and stability

Boule Con is shipped in a thermally insulated container designed to keep it cool. Sealed vials stored in an upright position at 2°C to 10°C, are stable at least up to the expiration date as shown on the product label. Open vial stability is 14 days after opening when returned to refrigerator after each use.

Indications of instability or deterioration

Inability to obtain expected values might indicate product deterioration. Discoloration of the product might be caused by overheating or freezing during shipping or storage. Darkly colored supernatant might be indicative of product deterioration, however, moderately colored supernatant is normal and should not be confused with product deterioration. If the recovered values are not within the expected ranges:

1. Review Instructions for use for the control product and the operating procedure of the instrument.
2. Check the expiration date of the Boule Con. Discard outdated products.
3. Test an additional unopened vial of Boule Con.

Instruction for use

Prerequisite: Remove the Boule Con sample tube from refrigeration and allow to warm at ambient temperature (18°C to 32°C) for 30 minutes before mixing.

Do not use a mechanical mixer to mix Boule Con.

1. Do the following:
   a. Hold the sample tube in an upright position between the palms of your hands and roll the tube slowly 8 times.
   b. Invert the tube and slowly roll it between the palms of your hands 8 times.
   c. Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time might require extra mixing.
   d. Gently invert the tube 8 times immediately before sampling.
2. For instructions for each sampling mode, refer to the user manual for your analyzer.
3. After open sampling, carefully wipe the rim of the tube and inside of the cap with a lint-free tissue. Replace the cap ensuring it is on tight.

4. Return the tubes to the refrigerator within 30 minutes of use.
5. Compare instrument values to those given in the Assay sheet available at www.boule.com. The instrument is considered well maintained and operating correctly if:
   - Recovered values fall within expected range.
   - Recovered values do not trend outside the expected range.

   Failure to achieve the listed conditions might indicate instrument and/or control problems. To identify the source of the problem, see investigational procedure section.
6. For consistency and best precision data, use the three levels of the cell control in the following order: abnormal low, normal, and abnormal high.
7. Before expiration of the current lot, good laboratory practice requires that a new lot of cell control be analyzed in parallel with the existing lot until a laboratory mean is established on the new lot.

Performance limits

Individual laboratories should expect better precision than that shown in the expected range column. Refer to your user manual for performance characteristics of precision for your instrument.

Precautions

RISK OF INFECTION
As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous. Refer to local regulations and established laboratory protocol for handling biohazardous materials.

CAUTION
Never use an opened vial longer than recommended by the manufacturer, past the expiration date, or subject any vial to excessive heat or agitation.

- For *in vitro* diagnostic use.
- Please read the relevant Safety Data Sheet (SDS) before use. SDSs are available at www.boule.com.
- This product should not be disposed in general waste but should be disposed with infectious medical waste. Disposal by incineration is recommended.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.
- Controls are not to be used as calibrators.

Serious incident

If a serious incident occurs in relation with Boule Medical's product, a notice shall be reported to the distributor, the manufacturer Boule and the competent authority of the Member State in which the user and/or the patient is established.

Hazard information

Any hazard related to the content of a consumable is indicated by a hazard code on the product label. See table below. For more information refer to the relevant Safety Data Sheet (SDS) at www.boule.com.

Hazard Code	Explanation
EUH 208	Contains a reaction mass of 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ON and 2-METHYL-2H-ISOTHIAZOL-3-ON. May produce an allergic reaction.
EUH 210	Safety Data Sheet available on request.

Investigational procedure

If you need help in resolving control recovery problems, call our customer service department. To provide faster handling of your inquiry, please have the following information available when you call:

- Expiration dates and lot numbers of all reagents, the control(s) in question and other levels of cell control that you use.
- Data supporting the problem for the lot number in question.
- Previous cell control lot numbers and the data you have for these previous lots.
- Data from a current reproducibility study (N=10) using a fresh whole blood specimen and performed according to your user manual.
- Data from your last instrument calibration.

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Meaning of symbols on product labels

REF	CONT	LOT
Article number	Content	Lot number
Manufacturer	Use-by date	Importer
CH REP	IVD	www.boule.com
Swiss authorized representative	*In vitro* diagnostic medical device	Consult electronic instructions for use available on website
Biohazard	Caution	Temperature limitation
CE	CONTROL	
CE marking of conformity	Control	

Ordering information and service

Contact your local Boule representative for orders and support. Please have the article number ready for orders. For other assistance contact Boule Medical AB at phone +46 8 7447700 or visit www.boule.com.

For a translation of this instruction, visit www.boule.com.

Article number	Description	Packaging
1504025	Boule Cal	1 x 3.0 ml
1504045	Boule Cal	2 x 3.0 ml
1504022	Boule Con-Diff Tri-Level, 16 parameter	6 x 4.5 ml
1504020	Boule Con-Diff Low, 16 parameter	1 x 4.5 ml
1504176	Boule Con-Diff Low, 16 parameter	6 x 4.5 ml
1504019	Boule Con-Diff Normal, 16 parameter	1 x 4.5 ml
1504043	Boule Con-Diff Normal, 16 parameter	6 x 4.5 ml
1504021	Boule Con-Diff High, 16 parameter	1 x 4.5 ml
1504216	Boule Con-Diff High, 16 parameter	6 x 4.5 ml

Contact information

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CH REP

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Regulatory information

Boule controls are considered general IVD devices under the In Vitro Diagnostic Directive 98/79/EC.

IVD CE